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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	10/779,892	TIPIRNENI, KISHORE			
Office Action Summary	Examiner	Art Unit			
	JAVIER G. BLANCO	3774			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
1) ☐ Responsive to communication(s) filed on 29 Ja 2a) ☐ This action is FINAL . 2b) ☐ This 3) ☐ Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro				
Disposition of Claims					
4) ☐ Claim(s) 1-26 is/are pending in the application. 4a) Of the above claim(s) 23, 24, and 26 is/are 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-22 and 25 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or Application Papers 9) ☐ The specification is objected to by the Examine 10) ☐ The drawing(s) filed on is/are: a) ☐ acce	withdrawn from consideration. r election requirement. r.	=xaminer			
Applicant may not request that any objection to the correction. Replacement drawing sheet(s) including the correction.	drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ate			

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 29, 2008 has been entered.

Response to Amendment

2. Applicant's amendment of claims 6, 11, and 17 in the reply filed on December 28, 2007 is acknowledged.

Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 17-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- **a.** Regarding claim 17, the limitation "said head component <u>having cutting threads</u>" (see line 6) lacks antecedent basis. Claims 18-21 depend on independent claim 17. <u>This was addressed in the previous office action</u>.

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Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

- 6. Claims 11-13 and 22 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.
- **a.** Regarding each of claim 11 (see "inserted into, and terminating within, said first bone portion"), claim 12 (see "said cap mates with said flexible wire against said second surface of said bone"), and claim 13 (see "a surgical plate mates with said second surface of said bone"), the Applicant positively recites part of a human. Thus claims 11-13 and 22 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-8, 14-16, and 25 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by HEHL (WO 00/67652 A2).

Referring to Figures 2-4, 6, 8, and 9, Hehl discloses a system including:

- (i) A head component 8 including a tip, cutting threads (see Figures 3 and 4), and fastening threads (as part of the cutting threads);
- (ii) A flexible wire 9 having a first end and a second end, and a first interface including a sawtooth configuration (shown in Figures 4, 6, and 9); and
- (iii) A cap 5, said cap having a second interface including an inverse sawtooth configuration (shown in Figures 4, 6, and 9). As part of the different embodiments, the second interface of the cap may include an inverse sawtooth configuration on an inner surface of the cap (see Figure 6, pawls 16). Hehl disclose that one or more pawls 16 could be used as part of the second interface. Said cap mates/pairs with said second end of said flexible wire by translating (as in a ratcheting system) along said flexible wire over a surface which restricts reverse translational movement (see Abstract). Cap 5 includes a flat surface, a center hole, and cutting/mating threads 20. Excess wire beyond the cap is removed (inherent in order to avoid exposing nearby/adjacent tissue to excess wire/cable, and clearly shown in Figures 3 and 4). A tool (e.g., driver) is capable of being attached to a portion of the head component. A tool/tensioner is used to apply tension the said wire (as in a ratcheting system).

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It should be noted that the adjective "flexible" is a broad term. Wire 9 comprises a long, thin shank/body, which will be subject to loads or forces. Said long, thin shank/body will inherently flex to some degree when exposed to said loads or forces. Further, Hehl discloses an embodiment of wire 9 as comprising a hollow material (see page 8, lines 22-25), which will inherently decrease its rigidity therefore increasing its flexibility. Additionally, the term "wire" is generally defined as a "slender rod". Wire 9 is in the shape of a slender rod.

NOTE: The intended use recitations (e.g., "configured to mate", etc.) carry no patentable weight in the absence of any distinguishing structure. The structure as claimed by HEHL is capable of performing the recited functional limitations if one desires so. Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

9. Claims 11, 12, 17-19, 21, and 22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Audren (FR 2 784 019 A3).

Referring to Figures 1 and 2, Audren discloses a system for the fixation of a bone fracture having a first bone portion and a second bone portion, said system including:

a. A head component (1) having cutting threads (clearly seen in the Figures), said head component inserted into, and terminating within, said first bone portion (see Figure 2);

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b. A flexible (see Figure 2) wire (2) comprised of a thin metal (e.g., titanium) having a first end, and a second end, wherein said flexible wire is at least one of bendable (i.e., capable of bending) without the use of tools and is able to be cut (i.e., capable of being cut) with a wire cutter, and wherein said first end of said flexible wire is affixed to said head component; and,

c. A cap (3) which mates, without rotation of said cap, with said second end of said flexible wire by translating along said flexible wire while an inside surface of said cap restricts reverse translational movement *to apply* pressure between said first bone portion and said second bone portion (e.g., friction, crimping, etc.). The cap comprises cutting threads (see Figures). The cap further comprises a substantially flat end, a center hole/bore receiving said flexible wire, and an additional opening/recess (located on the substantially flat end).

NOTE: The intended use recitations (e.g., "configured to mate", etc.) carry no patentable weight in the absence of any distinguishing structure. The structure as claimed by Audren is capable of performing the recited functional limitations if one desires so. Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

10. Claims 11-13, 17-19, and 21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bevan et al. (US 5,725,582 A).

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having a first bone portion and a second bone portion, said system including:

a. A head component (28) having cutting threads (clearly seen in the Figures), said head

Referring to Figures 3 and 4, Bevan et al. disclose a system for the fixation of a bone fracture

component inserted into, and terminating within, said first bone portion (see Figures);

b. A flexible (see Figures 3 and 4) wire (20/21) comprised of a thin metal having a first end, and

a second end, wherein said flexible wire is at least one of bendable (i.e., capable of bending)

without the use of tools and is able to be cut (i.e., capable of being cut) with a wire cutter, and

wherein said first end of said flexible wire is affixed to said head component; and,

c. A cap (26) which mates, without rotation of said cap, with said second end of said flexible

wire by translating along said flexible wire while an inside surface of said cap restricts (e.g.,

friction, crimping, etc.) reverse translational movement to apply pressure between said first bone

portion and said second bone portion. Surgical plates 30/31 may be used with the system.

NOTE: The intended use recitations (e.g., "configured to mate", etc.) carry no patentable weight

in the absence of any distinguishing structure. The structure as claimed by Bevan et al. is capable

of performing the recited functional limitations if one desires so. Claims directed to apparatus

must be distinguished from the prior art in terms of structure rather than function. *In re Danly*,

263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device

is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469,

15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof

during an intended operation are of no significance in determining patentability of the apparatus

claim. Ex parte Thibault, 164 USPQ 666, 667 (Bd. App. 1969).

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11. Claims 11, 12, 17-19, 21, and 22 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Muckter (US 2002/0198527 A1; cited in Applicant's IDS).

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Referring to Figures 1-4 and 8-13, Muckter discloses a system for the fixation of a bone fracture having a first bone portion and a second bone portion, said system including:

- **a.** A head component (Figure 1: component 2; Figure 2: component 6; Figure 3: component 9; Figure 4: component 10, which comprises tool/drill attachment 14) having cutting threads (clearly seen in the Figures), said head component inserted into, and terminating within, said first bone portion (see Figures 8-12);
- b. A flexible wire (wire cable or wire bundle 3, 5, 8, and 11) comprised of a thin metal having a first end, and a second end, wherein said flexible wire is at least one of bendable (i.e., capable of bending) without the use of tools and is able to be cut (i.e., capable of being cut) with a wire cutter, and wherein said first end of said flexible wire is affixed to said head component; and, c. A cap (Figure 1: cap 1; Figure 2: cap 4; Figure 3: cap 7; Figure 4: cap 13) which mates, without rotation of said cap, with said second end of said flexible wire by translating along said flexible wire while an inside surface of said cap restricts reverse translational movement (see paragraph 0040) to apply pressure between said first bone portion and said second bone portion (e.g., friction, crimping, etc.). The cap comprises cutting threads (see Figures). The cap further comprises a substantially flat end, a center hole/bore receiving said flexible wire, and an additional opening/recess (located on the substantially flat end).

NOTE: The intended use recitations (e.g., "configured to mate", etc.) carry no patentable weight in the absence of any distinguishing structure. The structure as claimed by Muckter is capable of performing the recited functional limitations if one desires so. Claims directed to apparatus must

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be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

12. Claims 11-13 and 17-21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Branch (US 5,520,691 A; cited in Applicant's IDS).

Referring to Figures 1-17, Branch discloses a system for the fixation of a bone fracture having a first bone portion and a second bone portion, said system including:

- **a.** A head component (83) having cutting threads (component 83 is disclosed as threaded, which treads will cut into bone tissue), said head component inserted into, and terminating within, said first bone portion;
- **b.** A flexible wire (82) comprised of a thin metal having a first end, and a second end, wherein said flexible wire is at least one of bendable (i.e., capable of bending) without the use of tools and is able to be cut (i.e., capable of being cut) with a wire cutter, and wherein said first end of said flexible wire is affixed to said head component; and,
- **c.** A cap (84) which mates, without rotation of said cap, with said second end of said flexible wire by translating along said flexible wire while an inside surface of said cap restricts reverse translational movement (see Figures 2, 4, 7, 8, 10, and 12) *to apply* pressure between said first bone portion and said second bone portion (e.g., friction, crimping, etc.). A tensioner 110, having

gauge 120, is used for applying tension to said flexible wire. Excess wire beyond the cap is removed (inherent in order to avoid exposing nearby/adjacent tissue to excess wire/cable, and clearly shown in Figure 9).

NOTE: The intended use recitations (e.g., "configured to mate", etc.) carry no patentable weight in the absence of any distinguishing structure. The structure as claimed by Branch is capable of performing the recited functional limitations if one desires so. Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Claim Rejections - 35 USC § 103

- 13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 14. Claims 1-22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dakin et al. (US 6,368,326 B1; cited in Applicant's IDS) in view of Cachia (US 5,893,850 A; cited in Applicant's IDS) and Fletcher (US 6,050,998).

Referring to Figures 1-5, Dakin et al. disclose a system including:

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(i) A head component (e.g., fastener 20) including a tip, cutting threads (20.4), and fastening threads (on the inside surface, or as part of the cutting threads on the outside surface);

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- (ii) A flexible wire (cord 22) having a first end and a second end; and
- (iii) A cap (first interpretation: fastener 24, which has cutting threads 24.2, bore 24.3, and interior threads 24.4; second interpretation: locking device/screw 28, which as threads 28.1; third interpretation: fastener 24 + locking device/screw 28), said cap mates/pairs with said second end of said flexible wire by translating along said flexible wire over a surface which restricts (e.g., by friction, or by crimping) reverse translational movement. Fastener 24 comprises a substantially flat end, a center hole 24.3, and additional openings 24.5, which additional openings are capable of expansion. The excess length of the second end of the flexible wire will be removed (inherent in order to avoid exposing nearby/adjacent tissue to excess wire/cable, and clearly shown in Figures 13), but the cap will engage the remaining portion of the second end of the flexible wire. A tool (e.g., driver) is capable of being attached to a portion of the head component (see entire document, particularly column 7, lines 8-14). A tensioner is used for applying tension to said wire (see, for example, Figure 1). A surgical plate is configured to mate with a surface of bone (see Figures).

The cap mates/pairs with the second end of the flexible wire. Notice in Figure 1 how a middle wire portion extends across an interface between a first bone portion 18 and a second bone portion 16. Notice in Figure 13 how a first end of the flexible wire is attached/mated/paired with the head component, and the second end of the flexible wire is attached/mated/paired with the cap.

The excess length of the second end of the flexible wire will be removed (clearly shown in Figures 13). Not only said limitation is inherent (in order to avoid exposing nearby/adjacent tissue to excess wire/cable), but additionally it is well known in the art. For example, Fletcher '998 teaches (see Figure 2, arrow 32; and Figure 9) removing excess length of the second end of a flexible wire (see column 3, lines 23-26) in order to avoid exposing nearby/adjacent tissue to excess wire/cable. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of removing excess length of a flexible wire, as taught by Fletcher, with the system of Dakin et al., in order to avoid exposing nearby/adjacent tissue to excess wire/cable.

Dakin et al. disclose the invention as claimed except for particularly disclosing the cap as comprising an inverse sawtooth configuration on an inner surface (e.g., bore) for translating along the flexible wire. However, this is already known in the art. For example, Cachia discloses a system comprising a cap/wire connection wherein the wire comprises a sawtooth configuration (retention structure 44) along at least a portion of said wire, and the cap comprises an inverse sawtooth configuration (retention structure 42) on an inner surface of said cap (see column 4, lines 23-32 and lines 50-67), wherein the cap translates along said wire in order to provide resistance to movement of the cap in the proximal direction relative to the wire (see column 4, lines 23-32 and lines 50-67). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a system comprising a cap/wire connection wherein the wire comprises a sawtooth configuration along at least a portion of said wire, and the cap comprises an inverse sawtooth configuration on an inner surface of said cap, wherein the cap translates along said wire, as taught by Cachia, with the

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system of Dakin et al., in order to provide resistance to movement of the cap in the proximal direction relative to the wire.

Response to Arguments

15. With regards to the 103(a) rejection based on Dakin et al. (US 6,368,326 B1; cited in Applicant's IDS) in view of Cachia (US 5,893,850 A; cited in Applicant's IDS), Applicant's arguments filed December 28, 2007 have been fully considered but they are not persuasive.

a. The Applicant argues the Examiner "has failed to identify a motivation to combine the teachings of Dakin and Cachia". The Examiner respectfully disagrees. The motivation to combined both references is clearly stated in the 103(a) rejection (above), i.e., "therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a system comprising a cap/wire connection wherein the wire comprises a sawtooth configuration along at least a portion of said wire, and the cap comprises an inverse sawtooth configuration on an inner surface of said cap, wherein the cap translates along said wire, as taught by Cachia, with the system of Dakin et al., in order to provide resistance to movement of the cap in the proximal direction relative to the wire".

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Figure 3 clearly shows a cap/plug that is not rotated (i.e., it does not have outer screw threads) but translated along flexible wire 22, which cap/plug comprises an inner

surface engaging flexible wire 22. When assembled, said inner surface restricts reverse translational movement. As seen in Figure 3, fastener 24, locking device/screw 28, and/or the above-indicated cap/plug can be broadly interpreted as the "cap". Cachia '850 teach the advantages of the interface between a sawtooth configuration along at least a portion of a wire/cord and an inverse sawtooth configuration on an inner surface of a cap/sleeve. Said teachings are applicable to either one of fastener 24, locking device/screw 28, and/or the cap/plug.

b. The Examiner has provided a reason to combine the references that will yield predictable results. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Javier G. Blanco/

Examiner, Art Unit 3774

/Dave Willse/

Primary Examiner, Art Unit 3738